

### **REMARKS**

Please reconsider the application in view of the above amendments and the following remarks. Applicant thanks the Examiner for carefully reviewing this application and for indicating that claims 6 and 20 contain allowable subject matter.

#### **Disposition of Claims**

Claims 1-24 were pending in this application. Claims 1, 8, and 18 are independent. The remaining claims depend, directly or indirectly, from these claims.

Claims 25-26 have been added. The new claims are fully supported by the original specification. No new matter was added.

#### **Rejections under 35 U.S.C § 102**

Claims 1-5, 7, 18-19, and 21-24 stand rejected under 35 U.S.C. § 102 as being anticipated by U.S. Published Patent Application No. 2004/0167498, by Azar et al. ("Azar"). Claim 1 has been amended in this response to include the disposing of a surface of a heat transfer element in close proximity to a suspected area of infection. Claims 2-4 and 7 have been amended to conform to amended claim 1. To the extent this rejection may apply to the amended claims, it is respectfully traversed.

Azar discloses a method and apparatus for treating acne using radiant energy, conducted through air to a hair, to destroy the hair, the hair follicle and/or one or more acne-related structures. Acne-related structures include a sebaceous gland, a papilla, bacteria such as *Propionibacterium acnes*, an acne cyst or nodule, an acne papule, an acne pustule, intrafollicular hyperkeratosis, a pilosebaceous follicle blockage, ingrown

hair, a sweat gland, a sweat gland duct, or a hemorrhagic follicular plug (Paragraphs 0013, 0124). Azar relies on a short duration of heating and/or preheating to avoid damage to the skin and states that *the rate of heat flow to the surrounding tissue is minimal* (Paragraph 0109).

As shown in Figs. 1-2, the Azar device uses a radiant heat source (114, 144, 244) disposed in a housing (120, 220) to radiate heat into an interior cavity of the housing, with the expectation that such heat will be absorbed by hairs (112) within the housing, and conducted thereby to one or more other acne-related structures. The method according to Azar, relies on the heating of air within the cavity to transfer heat to hair with the expectation that the hair will conduct the heat to one or more acne-related structures (Paragraphs 29 and 39). Notably, Azar neither discloses nor suggests any surface of a heat transfer element, nor are the radiant heat sources of Azar disposed such that they may be in close proximity to any suspected area of infection. Instead, the radiant heat sources simply heat air within a cavity.

In contrast to the method disclosed by Azar, claim 1, as amended, requires the disposition of a surface of a heat transfer element in close proximity to a suspected area of infection. Azar neither discloses nor suggests any surface of a heat transfer element, nor does Azar disclose or suggest disposing any such element in close proximity to a suspected area of infection. Instead, the configuration of the heating device according to Azar places any heating source at a distance from any suspected area of infection, and relies instead on heat conduction through air, and hair, to bridge the gap.

Furthermore, the method of amended claim 1 requires a *rapid* temperature change in a suspected area of infection. Many of the physiological mechanisms believed to

underlie the efficacy of embodiments of the instant invention rely to some extent on a “shock” to various metabolic systems, achieved by the *rapidity* of localized temperature changes, as well as the extent of such changes. Rapid temperature changes are believed by the Applicant to, among other things, decrease a pathogen’s rate of replication, denature proteins, constrict blood vessels, and otherwise inhibit certain natural pathways and physiological responses.

Azar neither suggests nor discloses a *rapid* temperature change in a suspected area of infection, and the configuration of Azar’s device is incompatible with any such rapid temperature change, due to the reliance on air to conduct thermal energy. Air is considered to be such a poor thermal conductor that it is commonly used as a thermal insulator. The heat transfer coefficient of air is only .024 W/m\*K. In contrast, wood, glass, and copper have heat transfer coefficients of .147 W/m\*K, 1.05 W/m\*K, and 401 W/m\*K, respectively (higher numbers indicate greater thermal conductivity). Azar’s reliance on air to conduct heat energy is thus incompatible with causing a rapid temperature change, as required by claim 1.

Furthermore, Azar specifically states that it may be desirable to conduct heat less rapidly into the skin, and specifies that the *rate of heat flow* to surrounding tissue is *minimal* (Paragraphs 0016, 0023, 0109). Accordingly, causing a rapid temperature change is neither disclosed nor suggested by Azar.

In view of the above, independent claim 1, as amended, is patentable over Azar. Claims 2-7, which depend from claim 1, are allowable for at least these same reasons. Accordingly, withdrawal of this rejection is respectfully requested.

Newly added claim 25 depends from claim 1 and is patentable over Azar for at least the same reasons as claim 1. Additionally, claim 25 includes the limitation that the rapid temperature change comprises cooling. Azar neither suggests nor discloses cooling. Therefore, claim 25 is patentable over Azar for this reason as well.

With respect to claims 18-19, and 21-24, Applicant respectfully requests clarification with respect to which portions of the Azar reference are considered relevant to these claims (*See* 37 C.F.R. 1.104(c)(2)). In the interim, to expedite prosecution of the instant application, Applicant respectfully traverses the rejection as follows:

Claim 18, as previously amended in Applicant's response of October 17, 2005, recites a method for using an apparatus for inhibiting infection, comprising positioning a surface of a heat transfer element in close proximity to a suspected area of infection, and activating the apparatus to cause a rapid temperature change in the suspected area of infection. As previously described with respect to claim 1, Azar fails to disclose or suggest a surface of a heat transfer element, placement of any such surface in close proximity to a suspected area of infection, or a rapid temperature change in a suspected area of infection.

The Azar device is a housing having an opening therein to form a cavity for enclosing a volume of air. Once the cavity is placed against a region of skin, the air within the cavity is heated, and the heat conducted through the air to one or more hairs and into one or more other acne-related structures. No surface of a heat transfer element is disclosed. Furthermore, the only portion of the Azar device that is positionable in close proximity to a subject is the gasket (118 in Fig. 1), which is not a heat transfer

element. As previously discussed, Azar relies on air to conduct heat, and therefore also fails to disclose or suggest a rapid temperature change in a suspected area of infection, as required by claim 18.

For at least these reasons, independent claim 18 is patentable over Azar. Claims 19-24, which depend from claim 18, are patentable for at least the same reasons. Accordingly, withdrawal of this rejection is respectfully requested.

Claims 8-17 stand rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 6,066,164, issued to Macher et al. ("Macher"). Claim 8 is amended in this response to include the limitation that the apparatus includes a positioning element. No new matter was added by way of this amendment, support for which may be found at least in Paragraph 0028 of the specification as filed, as well as Figs. 1-2. To the extent this rejection may apply to the amended claims, it is respectfully traversed.

Macher discloses a device for heating a skin surface. The Macher device includes a flat heat transfer element comprising at least one heating element formed of a plastic film and connected via a cable to a portable power supply apparatus. The Macher device preferably includes circuitry for regulating the flow of power between the heating element and an energy supply device. The device is suitable wherever a "pain-relieving, relaxing or similarly pleasant effect is required." Targeted conditions include rheumatic complaints, muscle tension, chills, menstrual complaints, nerve pain, and whiplash. Furthermore, the device may be utilized to keep warm any exposed body parts, and may thus be located in shoes or gloves. (Col. 4, ll. 50-64) The Macher device is configured for passive use at specific fixed locations on a subject's body, and is limited to external

applications. For instance, the Macher device may be disposed in gloves, worn as an armband, or attached to a body via adhesives. (Col. 2, ll. 14-20, Col. 8, ll. 16-30, Fig. 5)

In contrast to Macher, the apparatus of independent claim 8, as amended, is configured to be disposed in close proximity to a suspected area of infection, and thus includes a positioning element for active placement and positioning by an operator. This positioning element is also required for the application of varying degrees of pressure, as described in Paragraph [0034] of the instant application. The Macher device is not configured for such active placement and use, and accordingly does not include a positioning element as required by amended claim 8.

For at least this reason, independent claim 8, as amended, is patentable over Macher. Claims 9-17, which depend therefrom, are allowable for at least these same reasons. Accordingly, withdrawal of this rejection is respectfully requested.

Newly added claim 26 depends from independent claim 8, as amended, and is patentable over Macher for at least the same reasons as claim 8. Additionally, claim 26 includes the limitation that the predetermined temperature is lower than an initial temperature of the target area. Macher neither suggests nor discloses any configuration for cooling a target area. Therefore, claim 26 is patentable over Macher for this reason as well.

#### **Allowable Subject Matter**

Claims 6 and 20 have been indicated to be allowable if rewritten in independent form. For reasons set forth above, Applicant believes the independent claims, from

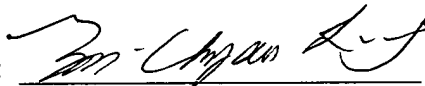
which claims 6 and 20 depend, are allowable. Therefore, Applicant respectfully defers rewriting claims 6 and 20 at this time.

### **Conclusion**

Applicant believes this reply is fully responsive to all outstanding issues and places this application in condition for allowance. If this belief is incorrect, or other issues arise, the Examiner is encouraged to contact the undersigned or his associates at the telephone number listed below. Please apply any charges not covered, or any credits, to Deposit Account No. 50-0591 (Reference No. 17090/002001).

Respectfully submitted,

Date: May 8, 2006

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